

The Sequence Listing

The examiner required that the Sequence Listing be corrected.

The applicant is herewith submitting a Sequence Listing section corrected according to the Patent Office guidelines, and a Declaration, and requesting that the computer readable version of the Sequence Listing section in ASCII be transferred from the parent application.

The attached Sequence Listing section is believed to place this application in conformity with the requirements of 37 CFR 1.821-1.825. Consideration thereof is hereby requested.

The Requirement for Restriction

The examiner has restricted the present claims to one of the following groups under 37 CFR 1.121:

Group I includes claims 52-60 directed to an antibody.

Group II includes claim 61 directed to a method for imaging.

Group III includes claim 62 directed to an in vivo method for delivering.

Group IV includes claims 63-64 directed to an ex vivo method of delivery targeted to neoplastic cells.

The examiner indicates that the product may be used for more than one purpose and the methods practiced with other products.

This is clearly not the case. The applicant wishes to point to the examiner that all method claims are custom tailored for practice only with the antibody of the invention.


Should the examiner, however, maintain the grounds for restriction, she is requested to rejoin the use claim 61 (Group II) upon a finding of allowable subject matter.

In view of the foregoing amendments and remarks, this application is believed to be in condition for examination on the merits, and for allowance.

Respectfully submitted.
CANCER RESEARCH INSTITUTE

November 3, 2003

Date



Viviana Amzel, Ph.D.
Reg. No. 30,930
Agent for the Applicant

P.O.Box 159
Gladwyne, PA 19035
610-649-0609 Ph.
240-359-0299 Fax

I hereby certify that this paper and fee is being deposited with the United States Postal Service "First Class Mail" service under 37 CFR 1.8 on November 3, 2003, and is addressed to the Assistant Commissioner for Patents, Alexandria VA 22312, by Viviana Amzel.



SIGNATURE

**WHAT IS SEEKED TO BE PATENTED AS NOVEL & UNOBVIOUS
IN LETTERS PATENT OF THE UNITED STATES IS:**



52. Canceled.

53. Canceled.

54. Canceled.

55. Canceled.

56. Canceled.

57. Canceled.

58. Canceled.

59. Canceled.

60. Canceled.

61. Canceled.

62. Canceled.

63. Canceled.

64. Canceled.

65. (Previous claim 52) A specifically targeted antibody, comprising a monoclonal antibody selectively binding the 46 Kd MW human milk fat globule (HMFG) differentiation antigen, which has an affinity constant for the antigen of about 10^{10} to $10^5 M^{-1}$, operatively linked to an agent comprising an immunotoxin or a detectable label.

66. (New) The antibody of claim 65, wherein the labeled or therapeutic agent comprises a radionuclide, a fluorescent label, an immuno-toxin, an enzyme or biotin.

67. (Previous claim 53) The antibody of claim 66, wherein the labeled or therapeutic agent comprises a radionuclide.

68. (New) The antibody of claim 66, wherein the labeled or therapeutic agent comprises a fluorophore.

69. (New) The antibody of claim 66, wherein the labeled or therapeutic agent comprises an immuno-toxin.

70. (New) The antibody of claim 66, wherein the labeled or therapeutic agent comprises an enzyme.

71. (New) The antibody of claim 66, wherein the labeled or therapeutic agent comprises biotin.

72. (New) The antibody of claim 71, wherein the labeled agent is detected as a conjugate.

73. (New) The antibody of claim 72, wherein the antibody is conjugated to avidin, streptavidin, or a magnetic bead.

74. (Previous claim 55) The antibody of claim 65, wherein the antibody comprises a monoclonal antibody.

75. (Previous claim 56) A composition comprising the antibody of claim 65, and a non proteolytic carrier.

76. (Previous claim 57) The composition of claim 75, wherein the carrier comprises a biologically acceptable carrier.

77. (Previous claim 58) The composition of claim 75, wherein the carrier comprises a pharmaceutically acceptable carrier.

78. (Previous claim 59) An anti-neoplastic kit, comprising
the specifically targeted antibody of claim 65 or a composition thereof; and
instructions for its use.

79. (Previous claim 60) The anti-neoplastic kit of claim 78 comprising, in separate containers,

the monoclonal antibody in unlabeled form;

a labeled or therapeutic agent; and

instructions for linking the antibody and the agent, for administration of the linked antibody-agent, and for use of the kit.

80. (New) The anti-neoplastic kit of claim 79, wherein the labeled agent comprises an immunotoxin(s) or a radionuclide(s).

81. (Previous claim 61) An in vivo method of imaging a neoplasia of epithelial origin, comprising

administering to a subject suspected of being afflicted with a neoplasia an amount of the labeled or unlabeled agent of claim 65, under conditions effective to deliver it preferentially to target neoplastic cells of epithelial origin in the subject's body to form antibody-cell antigen complexes;

administering to the subject a detectable labeled agent binding the antibody at a site other than the binding site for the 46 kDalton HMFG polypeptide if the antibody is unlabeled; and

detecting the presence of any label in the subject's body.

82. (New) The method of claim 81, wherein the antibody is administered intravenously, intraperitoneally, intracavitarily, intra-tumor, intramuscularly, or into the lymphatic system.

83. (New) The method of claim 81, wherein the labeled agent comprises a fluorescent or radiolabeled agent.

84. (New) The method of claim 81, wherein

the antibody administered comprises an unlabeled antibody; and

the labeled agent administered comprises a labeled anti-antibody immunoglobulin or antibody binding fragment thereof.

85. (Former claim 62) An in vivo method of delivering a therapeutic agent to target neoplastic cells of epithelial origin, comprising

binding a therapeutic agent to the antibody of claim 65, at a site other than its antigen binding site;

administering to a subject suspected of being afflicted with a neoplasia of epithelial origin, a therapeutically effective amount of the antibody-bound therapeutic agent under conditions effective to deliver the agent to target neoplastic cells; and

allowing the antibody to bind to the neoplastic cells, and the therapeutic agent to exert its effect on the cells.

86. (Former claim 63) An ex vivo method of delivering a therapeutic agent to target neoplastic cells, comprising

obtaining a sample from a subject suspected of being afflicted with a neoplasia of epithelial origin;

adding to the sample the therapeutic agent of claim 65, under conditions effective to promote the formation of antibody-cell complexes;

allowing the agent to exert its effect on the cells; and

returning the sample to the subject.

87. (Former claim 64) The method of claim 86, further comprising separating antibody-bound materials from the sample prior to returning it to the subject.